European Medicines Agency
Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

CONCEPT PAPER ON THE REVISION OF THE NOTE FOR GUIDANCE ON RADIOPHARMACEUTICALS

AGREED BY QUALITY WORKING PARTY	February 2006
ADOPTION BY CHMP FOR RELEASE FOR CONSULTATION	23 March 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	30 May 2006

Note: The proposed guideline replaces the Note for Guidance on Radiopharmaceuticals (Eudralex 3AQ20a)

Comments should be provided to QWP@emea.eu.int

KEYWORDS	Radiopharmaceuticals, positron emitting radiopharmaceuticals, PET, quality

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1. INTRODUCTION

The current Note for Guidance on Radiopharmaceuticals (Eudralex 3AQ20a) was last revised in December 1990.

2. PROBLEM STATEMENT

A concept paper for a multidisciplinary revision of this Note for Guidance on Radiopharmaceuticals (Eudralex 3AQ20a) was proposed on 17 December 1998, to embrace quality, preclinical and clinical aspects. Since then, non-clinical and clinical aspects have been included in the revised Annex 1 to Directive 2001/83/EC as amended. Therefore, this concept paper addresses the need to update the existing Note for Guidance on "Radiopharmaceuticals" to the current state of the art, and to focus particularly on quality aspects.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

With regard to quality guidelines in general, radiopharmaceuticals are excluded from the scope of some Notes for Guidance and not from others. For each Note for Guidance, it should be investigated which sections of the given guidance are applicable to radiopharmaceuticals and/ or where additional specific guidance must be given.

The revised Note for Guidance should be aligned with the monograph "Radiopharmaceuticals" of the Ph.Eur especially regarding terminology.

Guidance should be given on the compilation of marketing authorisation application dossiers for radiopharmaceutical medicinal products, which are described in the Ph. Eur. as a finished dosage monograph. For such products, the dossier should deal with the quality aspects that are specific to the applied manufacturing process and manufacturing site.

4. RECOMMENDATION

- To revise the Note for Guidance on radiopharmaceuticals focusing on the quality aspects.

- To include Positron Emitting radiopharmaceuticals in the revised guideline.

5. TIMETABLE

6. RESOURCE REQUIREMENTS FOR PREPARATION

In accordance with the QWP workprogramme for 2006, it is suggested that a drafting group consisting of four experts on quality aspects of Radiopharmaceuticals meets once at the EMEA during 2006 and if necessary again during 2007, to revise the existing Note for Guidance on Radiopharmaceuticals with regard to quality aspects.

It is considered that much of the work of the group can be carried out by e mail or fax with the need for a limited number of meetings (carried out in association with QWP meetings).

The EMEA is asked for technical support. Draft versions of the revised documents will be presented to the different working parties for comment.

7. IMPACT ASSESSMENT (ANTICIPATED)

The revision of the guideline will allow to reach a uniform approach in the EU for these specific medicinal products and to harmonise data requirements for industry. It will ease assessment for regulators.

8. INTERESTED PARTIES

- European Association of Nuclear Medicine (EANM)

- EFPIA

9. REFERENCES TO LITERATURE, GUIDELINES ETC

1. Note for Guidance on Radiopharmaceuticals (Eudralex 3AQ20a)